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## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

AUG 18 2009

### 1.0 submitter's information

Name: Andon Health Co., Ltd.  
Address: No 31, Changjiang Road, Nankai District, Tianjin,  
P.R. China  
Phone number: 86-22-6052 6161  
Fax number: 86-22-6052 6162  
Contact: Liu Yi  
Date of Application: 05/27/2009

### 2.0 Device information

Trade name: Semi Automatic Electronic Blood Pressure Monitor  
Common name: Noninvasive blood pressure measurement system  
Classification name: Noninvasive blood pressure measurement system

### 3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.  
Regulation number: 870.1130  
Classification: II  
Panel: Cardiovascular

### 4.0 Predict device information

Manufacturer: Andon Health Co., Ltd.  
Device: KD-322 Semi Automatic Electronic Blood Pressure Monitor  
510(k) number: K083395

### 5.0 Device description

KD-388BD Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

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It is designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmomanometers.

The operational principle is based on oscillometric and silicon integrate pressure sensor technology, the result will be shown on a LCD with an electronic interface module, the memory capability of KD-388BD is 2×60 times.

#### **6.0 Intended use**

KD-388BD Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

The intended use and the indication for use of KD-388BD, as described in their labelings are the same as the predicate device KD-322.

#### **7.0 Summary comparing technological characteristics with predicate device**

<b>Technological Characteristics</b>	<b>Comparison result</b>
Design principle	Identical
Appearance	Similar
Patients contact Materials	Similar
Performance	Similar
Biocompatibility	Similar
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

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## **8.0 Performance summary**

KD-388BD Semi Automatic Electronic Blood Pressure Monitor conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 --, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 --, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

## **9.0 Comparison to the predict device and the conclusion**

Our device KD-388BD Semi Automatic Electronic Blood Pressure Monitor is substantially equivalent to the Semi Automatic Electronic Blood Pressure Monitor KD-322 whose 510(k) number is K083395.

KD-388BD and KD-322 are very similar in the intended use, the design principle, the material, the energy source and the applicable standards. Only their appearance and some functions such as 2×60 times memory and TIME/DATE display are added. The performance parameter of cuff pressure range and overpressure limit are different from the predicted device KD-322. The pulse rate range is changed from 30-180 times/min to 40-180 times/min, KD-388BD also adds a new cuff.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-0609  
Silver Spring, MD 20993-0002

**AUG 18 2009**

Andon Health Co., Ltd.  
c/o Mr. Liu Yi  
No 31 Changjiang Road  
Nankai District, Tianjin  
China 300190

Re: K091738  
Trade/Device Name: KD-388BD Semi Automatic Electronic Blood Pressure Monitor  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: undated  
Received: July 21, 2009

Dear Mr. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

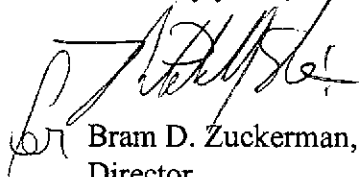
Page 2 – Mr. Liu Yi

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Statement of Indications for Use

**510(k) Number :** K091738

**Device name:** KD-388BD Semi Automatic Electronic Blood Pressure Monitor

**Indications for use:**

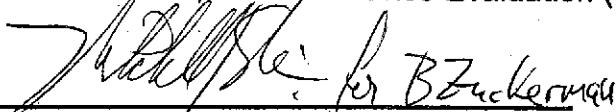
KD-388BD Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use \_\_\_\_\_ AND/OR Over-The-Counter Use YES  
Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

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